DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 2, 2015

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park
Nanshan, Shenzhen 518057, P.R. China

Re: K150352
Trade/Device Name: V Series Monitoring System (including V12 And V21 Monitors)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DRT, DXN, DSK, FLL, DQA, CCK, CBS, CBR, CCL, DXG, DQK, MUD, BWM, NHO, CBQ, NHQ, NHP
Dated: July 31, 2015
Received: August 4, 2015

Dear Yanhong Bai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K150352

Device Name
V Series Monitoring System (including V12 and V21 Monitors)

Indications for Use *(Describe)*
The V Series Monitoring System is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The Indications for Use for the V12/V21 Monitor include the continuous monitoring of the following human physiological parameters:

- ECG waveform derived from 3, 5 and 12 Lead measurements
- Heart Rate
- ST Segment Analysis
- Arrhythmia Detection
- 12-lead ECG interpretation
- QT Analysis
- Pulse Oximetry (SpO2)
- Pulse Rate (PR)
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP)
- Cardiac Output (C.O.)
- Respiratory Gases (O2, CO2)
- Respiration Rate (RESP)
- Anesthetic Gases (Iso, Enf, Sev, Hal, Des, N2O)
- Temperature (TEMP)
- Bispectral Index (BIS)

The V12/V21 Monitor has the capability of performing IV Drug and Hemodynamic Calculations and interfacing with network devices.
The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection, ST Segment Analysis and QT Analysis, for which the target population are adult and pediatric only,
- IV Drug Calculations for which the target population is adult only,
- Cardiac Output for which the target population are adult and pediatric only, and
- Bispectral Index(BIS) for which the target population are adult and pediatric only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K150352

Page 2 of 2

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5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the V Series Monitoring System is provided below.

Device Common Name: Multi-Parameter Patient Monitor (with arrhythmia detection or alarms)

Device Proprietary Name: V Series Monitoring System (including V12 and V21 Monitors)

Submitter:
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Contact:
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Date Prepared: January 29, 2015

Classification Regulation: 21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Panel: Cardiovascular

Classification Regulation, Classification Name and Product Codes:

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
Primary				
MHX	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Monitor, physiological, patient (with arrhythmia detection or alarms)
Secondary				

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
DSI	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Detector and alarm, arrhythmia
MLD	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Monitor, st segment with alarm
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, cardiac (incl. cardiotachometer & rate alarm)
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	System, measurement, blood-pressure, non-invasive
DSK	21 CFR 870.1110	Cardiovascular	Blood pressure computer	Computer, blood-pressure
FLL	21 CFR 880.2910	Cardiovascular	Clinical electronic thermometer	Thermometer, electronic, clinical
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	Oximeter
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer	Analyzer, gas, carbon-dioxide, gaseous-phase
CBS	21 CFR 868.1620	Anesthesiology	Halothane gas analyzer	Analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBR	21 CFR 868.1700	Anesthesiology	Nitrous oxide gas analyzer	Analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CCL	21 CFR 868.1720	Anesthesiology	Oxygen gas analyzer	Analyzer, gas, oxygen, gaseous-phase
DXG	21 CFR 870.1435	Cardiovascular	Single-function, preprogrammed diagnostic computer	Computer, diagnostic, pre-programmed, single-function
DQK	870.1425	Cardiovascular	Programmable diagnostic computer.	Computer, diagnostic, programmable
MUD	870.2700	Cardiovascular	oximeter	Oximeter, tissue saturation
GWM	822.1620	Neurology	Intracranial pressure monitoring device	Device, monitoring, intracranial pressure
NHO	868.1500	Anesthesiology	Enflurane gas analyzer	Analyzer, gas, desflurane, gaseous-phase (anesthetic concentration)
CBQ	868.1500	Anesthesiology	Enflurane gas analyzer	Analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
NHQ	868.1500	Anesthesiology	Enflurane gas analyzer.	Analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
NHP	868.1500	Anesthesiology	Enflurane gas analyzer	Analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)

Predicate Device:

K132026 - V Series Monitoring System (including V12 and V21), MINDRAY DS USA, INC.

K143195 - Passport Series Patient Monitors (including Passport 17M, Passport 12M and T1), Shenzhen Mindray Bio-Meidcal Electronics Co., Ltd.

K101521 - ST/AR ST AND ARRHYTHMIA SOFTWARE, PHILIPS MEDICAL SYSTEMS.

Indications for Use:

The V Series Monitoring System is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The Indications for Use for the V12/V21 Monitor include the continuous monitoring of the following human physiological parameters:

- ECG waveform derived from 3, 5 and 12 Lead measurements
- Heart Rate
- ST Segment Analysis
- Arrhythmia Detection
- 12-lead ECG interpretation
- QT Analysis
- Pulse Oximetry (SpO2)
- Pulse Rate (PR)
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP)
- Cardiac Output (C.O.)
- Respiratory Gases (O2, CO2)
- Respiration Rate (RESP)
- Anesthetic Gases (Iso, Enf, Sev, Hal, Des, N2O)
- Temperature (TEMP)
- Bispectral Index (BIS)

The V12/V21 Monitor has the capability of performing IV Drug and Hemodynamic Calculations and interfacing with network devices.

The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection, ST Segment Analysis and QT Analysis, for which the target population are adult and pediatric only,
- IV Drug Calculations for which the target population is adult only,
- Cardiac Output for which the target population are adult and pediatric only, and
- Bispectral Index (BIS) for which the target population are adult and pediatric only.

Device Description:

The subject V Series Monitoring System includes two monitors, one incorporating a12" display (V12 Monitor) and the other incorporating a 21" display (V21 Monitor), and includes the following system components:

- Display Control Unit (DCU) - Display Control Unit (DCU) includes the system processor, monitor display, user interface and appropriate connectors for communication to peripheral devices. The 12-inch (V12) monitor display features a touch screen display that accommodates up to 8 waveforms and corresponding numerics. It includes an internal module rack in the back which holds up to 6 modules, depending on their size. It can be removed from the docking station and used as an intra hospital transport monitor. The 21-inch (V21) monitor display features a touch screen display that accommodates up to 12 waveforms and corresponding numerics. It also includes a touch pad as an optional method to interact with the software.
- Docking Station (Model name: V Dock) - The Docking Station is a physical mount for the DCU. The Docking Station incorporates multiple connectivity ports designed to enable quick connection and release for mobility. It provides power to the monitoring system. It features a quick release mechanism that allows the DCU to be easily and quickly removed and reattached. The docking station also provides connectivity to other external devices and systems such as remote displays or nurse call systems and mounts to a wall mount or rolling stand. The Docking Station used in the subject V Series is referred to in Mindray internal documents as "V Dock" or "Dock".
- Module Rack (Model name: V Hub) - The Module Rack is a physical mount for the modules capable of holding up to 6 modules, depending on their size. It features a quick release mechanism that allows the Module Rack to be easily and quickly removed and reattached to a wall mount or rolling stand to be used during intra hospital transports. The Module Rack used in the subject V Series is referred to in Mindray internal documents as "V Hub" or "Hub".
- VPS Module - The VPS is the main parameter module of the subject V Series that provides the core parameters: 3/5/12-lead ECG, SpO2, Respiration, NIBP, 2 invasive pressures and 1 temperature channel. The VPS is a parameter acquisition device designed to acquire and store real-time vital sign data. Its modular design allows it to be moved with the patient between V Series Monitoring Systems.
- Modules - Modules are data acquisition devices that add parameter and interface capability to the subject V Series. These modules are parameter specific and include temperature, invasive blood pressure (IBP), cardiac output (C.O.), CO2, and strip recorder. One module, the VDI (V Device Integrator), is configurable to allow interface to other medical devices such as continuous cardiac output (CCO), regional oxymetry saturation (rSO2), respiratory gas, and DIAP (previously cleared under the

predicate V Series K132026). One module, the BIS interface module, is configurable to allow interface to BIS module (Mindray is seeking clearance for this new feature under this 510(k)).

- View 12 (12 lead ECG cable) - The View 12 will monitor 12 lead ECG and respiration through the ECG port connection on the VPS Module.

Performance Data:

- To establish the substantial equivalence of the V Series Monitoring System (including V12 and V21 Monitors), Mindray conducted system and performance testing on the subject devices. The testing provided an evaluation of the performance of the device relevant to each of the modifications to the subject devices since their previous clearance. The system and performance testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.
- Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.
- Mindray has also followed the FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm issues on October 28, 2003.
- The V Series Monitoring System has been modified to provide wireless functionality. Mindray conducted Wireless functionality testing to ensure the performance of the new wireless modules meet specifications and are equivalent to the predicate device.

Consensus Standards

The subject V Series Monitoring System has been tested and found to be in compliance with the following safety and performance standards:

- ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-2-49:2011
- IEC 60601-1-2:2007
- IEC 60601-1-8:2012
- IEC 60601-1-6: 2013
- IEC 60601-2-25:2011
- IEC 60601-2-27:2011
- ANSI/AAMI EC57: 2012
- IEC 60601-2-34:2011
- IEC 80601-2-30:2013
- ISO 81060-2: 2013
- ISO 80601-2-56: 2009
- ISO 80601-2-61: 2011
- IEC 60601-2-26:2002
- ISO 80601-2-55: 2011

Substantial Equivalence:

Comparison of Indications:

Both the predicate and the subject V Series are multi-parameter patient monitors intended to be used in healthcare facilities under the direction of clinical professionals. The indications for use of the subject V Series have been modified to:

- remove the feature of ECG waveform derived from 6 lead measurements from the subject V Series
- include the addition of a QT analysis feature and the interface to and display of Bispectural Index (BIS)

For business reasons only, Mindray has decided to remove the feature of ECG waveform derived from 6 lead measurements from the subject V Series. Removal of this feature does not affect the safety and effectiveness of the subject device. So this change does not impact substantial equivalence.

Although the addition of the interface to and display of Bispectral Index (BIS) and QT Analysis feature are not presented in the primary predicate device V Series, the Bispectral Index (BIS) is presented in the cleared Passport Series (K143195), QT Analysis is presented in the cleared Philips (K101521), and thus does not constitute a new intended use for a multi-parameter monitor.

In conclusion, the changes to the indications for use do not change the fundamental intended use of the V Series as multi-parameter monitors.

Comparison of Technological Characteristics:

The table below compares the key technological feature of the subject V Series to the primary predicate V Series (K132026). The features highlighted in grey are the features that have been modified since their previous clearances and that are the subject of this 510(k) for which Mindray is seeking clearance.

Device Comparison Table

	Predicate Device / V Series (K132026)		**Subject Devices**	
Feature	**V12**	**V21**	**V12**	**V21**
Integrated display and touch screen	12.1" TFT 1024 x 768 pixels	21.3" TFT 1600 x 1200 pixels	Same	Same
Secondary display	Display is linked to integrated display		Same	Same

	Predicate Device / V Series (K132026)		**Subject Devices**	
Feature	**V12**	**V21**	**V12**	**V21**
Module rack	Independent of the patient monitor, provides 1 integrated and 2 extended module slots to extend the measurement capabilities of the system	Independent of the patient monitor, provides 3 extended module slots to extend the measurement capabilities of the system	Same	Same
Power supply	Three rechargeable Lithium-ion battery(maximum) or AC power supply	AC power supply	Same	Same
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4.8 Ah (one battery)	Not supported	Same	Same
External memory card	USB Memory Stick		Same	Same
Data Recorder	The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.		Same	Same
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones, warning tone; support PITCH TONE and multi-level tone modulation.		Same	Same
Printer	Laser Printer and Thermal Printer (the addition of the Strip Chart Recorder Module supports the thermal printer)		Same	Same
ECG waveform	3-lead , 5-lead, **6-lead** or 12-lead selectable		3-lead , 5-lead or 12-lead selectable	3-lead , 5-lead or 12-lead selectable

	Predicate Device / V Series (K132026)		**Subject Devices**	
Feature	**V12**	**V21**	**V12**	**V21**
Heart Rate Meter (ECG)	Measurement range: 3, 5 / 6 lead: Adult/Pediatric:**30**-300 bpm; Neonatal:**30**-350bmp 12 lead: Adult/Pediatric:**30**-300 bpm; Neonatal: **30**-350bpm Accuracy: ± 3 bpm or ± 3% in the range of **30** to 250 bpm, whichever is greater ± 5% in the range of 251 bpm to 350 bpm		Measurement range: 3, 5lead: Adult/Pediatric:**20**-300 bpm; Neonatal:**20**-350bpm 12 lead: Adult/Pediatric:**20**-300 bpm; Neonatal :20-350bpm Accuracy: ± 3 bpm or ± 3% in the range of **20** bpm to 250 bpm, whichever is greater ± 5% in the range of 251 bpm to 350 bpm	Measurement range: 3, 5lead: Adult/Pediatric:**20**-300 bpm; Neonatal:**20**-350bpm 12 lead: Adult/Pediatric:**20**-300 bpm; Neonatal:**20**-350bpm Accuracy: ± 3 bpm or ± 3% in the range of **20** bpm to 250 bpm, whichever is greater ± 5% in the range of 251 bpm to 350 bpm
QRS waveform detection	Supported, **fixed threshold 0.2mV**		Supported, **adjustable threshold between 0.16mV to 0.48mV**	Supported, **adjustable threshold between 0.16mV to 0.48mV**
ST Segment Analysis	Supported		Same	Same
Arrhythmia Detection	Supported, **fixed leads for arrhythmia analysis**		Supported, **adjustable leads for arrhythmia analysis,** **Added Extreme Bradycardia alarms, Extreme Tachycardia alarms, Pacer Failure to Capture alarms, Pacer Failure to Sense alarms**	Supported, **adjustable leads for arrhythmia analysis** **Added Extreme Bradycardia alarms, Extreme Tachycardia alarms, Pacer Failure to Capture alarms, Pacer Failure to Sense alarms**
12-lead ECG interpretation	Supported		Supported **Added Baseline Drift Removal (BDR) filter, Muscle Artifact filter and Beat markers**	Supported **Added Baseline Drift Removal (BDR) filter, Muscle Artifact filter and Beat markers**
QT Analysis	Not supported		Supported	Supported

	Predicate Device / V Series (K132026)		**Subject Devices**	
Feature	**V12**	**V21**	**V12**	**V21**
The version of Mortara arrhythmia algorithm analysis software	**3.3.5**		**4.0.0**	**4.0.0**
Pace Detection	**Single Pace detection channel**		**Dual Pace detection channels**	**Dual Pace detection channels**
Pulse oxygen saturation (SpO2)	SpO2 Range：70-100% SpO2 Accuracy Nellcor: With sensor: MAXAI, MAX-AL, MAXPI, MAXII, MAXNI (Adult), MAXNI (Neonate) 70% to 100% ± 2 digits With sensor: OxiCliq A, OxiCliq P, OxiCliq I, OxiCliq N(Adult), OxiCliq N (Neonate) 70% to 100% ± 2.5 digits With sensor :DS-100A, D-YS (Infant to Adult), OXI-A/N (Adult), OXI-P/I 70% to 100% ± 3 digits With sensor :D-YS with D-YSE Ear Clip, D-YS with D-YSPD Spot Clip 70% to 100% ± 3.5 digits With sensor :D-YS (Neonate), OXI-A/N (Neonate) 70% to 100% ± 4 digits Masimo: Adult,pediatric: Maximum error of 2% with no motion Maximum error of 3% in the presence of motion with motion resistant sensors. Neonatal: Maximum error of 3%		Same	Same

<table>
<tr><td></td><td colspan="2">Predicate Device / V Series (K132026)</td><td colspan="2">Subject Devices</td></tr>
<tr><td>Feature</td><td>V12</td><td>V21</td><td>V12</td><td>V21</td></tr>
<tr><td>Pulse rate (PR)</td><td colspan="2">PR range:
Nellcor:20-249 bpm
Masimo:26-239 bpm
PR Accuracy: ± 3bpm</td><td>Same</td><td>Same</td></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td colspan="2">Measurement Technique: Oscillometric
Pressure Measurement range(mmHg):<table><tr><td></td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr><tr><td>Systolic</td><td>55 to <u>235</u></td><td>55 to <u>160</u></td><td>45 to <u>120</u></td></tr><tr><td>Diastolic</td><td>30 to 200</td><td>30 to 150</td><td>20 to 100</td></tr></table>Accuracy:
Max mean error: ±5 mmHg
Max standard deviation: 8 mmHg
Pulse Rate Range(bpm):
Adult/Pediatric: 35 - 245
Neonatal: 70-245</td><td>Measurement Technique: Oscillometric
Pressure Measurement range(mmHg):<table><tr><td></td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr><tr><td>Systolic</td><td>55 to <u>270</u></td><td>55 to <u>170</u></td><td>45 to <u>130</u></td></tr><tr><td>Diastolic</td><td>30 to 200</td><td>30 to 150</td><td>20 to 100</td></tr></table>Accuracy:
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Max mean error: ±5 mmHg
Max standard deviation: 8 mmHg
Pulse Rate Range(bpm): Adult/Pediatric: 35 - 245
Neonatal: 70-245</td></tr>
<tr><td>Invasive blood pressure (IBP)</td><td colspan="2">Accuracy:
± 2mmHg or 2% whichever is greater
Zero Offset Range:
± 120 mmHg
IBP Heart Rate range:
30 to 300 bpm(Adult/Pediatric), 30 to 350 bpm(Neonatal)
IBP Heart Rate accuracy:
± 3 bpm or ± 3%, whichever is greater at 30 to 250 bpm,
±5 BPM or ±5 from 251 to 350 BPM</td><td>Same</td><td>Same</td></tr>
</table>

	Predicate Device / V Series (K132026)		**Subject Devices**	
Feature	**V12**	**V21**	**V12**	**V21**
Cardiac output (C.O.)	The temperature change is displayed as a curve in the C.O. split screen, and the monitor calculates the C.O. value from this curve. C.O. Range: 0.2 to 20.0 liters/minute C.O. Accuracy: 5% or 0.2 liters/minute, whichever is greater Blood Temperature Range: 17.5 - 43°C (63.5°F - 109.4°F) Blood Temperature Accuracy: ± 0.2°C (± 0.4°F), exclusive of probe errors Injectate Temperature Range: (-)1.0 to 30.0 °C (30.2° F to 86° F) Injectate Temperature Accuracy: ± 0.2°C (± 0.4°F), exclusive of probe errors		Same	Same
Capnography (EtCO2 and FiCO2)	Measurement range: 0-99 mmHg Accuracy: 0-38 mmHg :± 2 mmHg 39-99 mmHg : ± (5% of reading +0.08% for every 1 mmHg over 38 mmHg) Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ± 12% of reading whichever is greater, for EtCO2 values exceeding 18 mmHg. Respiration Rate range (respriations per minute): 0 to 150 rpm Respiration Rate Accuracy: ± 1 rpm from 0 to 70 rpm, ± 2 rpm from 71 to 120 rpm, ± 3 rpm from 121 to 150 rpm		Same	Same

	Predicate Device / V Series (K132026)		**Subject Devices**	
Feature	**V12**	**V21**	**V12**	**V21**
Respiration rate (Resp)	Measurement range: 4 rpm to 199 rpm; Accuracy: ± 2 or ± 2%, whichever is greater from 4 to 150, ± 4% from 151 to 199		Same	Same
Temperature (Temp)	Measurement range: 15-45°C(59-113°F) Accuracy: ±0.1°C (15°C to 45°C) exclusive of probe errors or ± 0.2°F (59°F to 113°F) exclusive of probe errors		Same	Same
Bispectral index (BIS)	Not supported		Supported	Supported
14 new NIBP cuffs	None		Supported	Supported
Wireless functionality	Not supported		Supported	Supported

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the identified predicate devices, the performance testing and conformance with applicable standards, the subject V Series has been demonstrated performance that is substantially equivalent to the predicate device.